

**REMARKS**

Examiner Snow is thanked for withdrawing previous rejections under Section 112 and objections. The pending Office Action alleged anticipation and obviousness concerning the pending claims. Reconsideration is respectfully requested in light of the following remarks.

Comments Regarding Previously-Submitted Declaration

The declaration submitted previously was provided for consideration with the application information of record, as explained in the prior response, so as to antedate the German reference, DE 202 05 016. The pending Action indicated that it was insufficient to overcome the reference insofar as the declarant is not an inventor, and insofar as it does not adequately demonstrate conception. It is acknowledged that that declarant is not an inventor. Even so, as discussed further below, that declaration provides relevant information concerning at least diligence that the Examiner should consider. A declaration from inventor Simonton has now been obtained, and its consideration is respectfully requested.

The Rejections Over the German Reference Should Be Withdrawn

The Office Action again rejected the non-withdrawn claims as either anticipated by or obvious in view of the German reference. These rejections should be withdrawn for at least two reasons. First, the German reference is not proper prior art, as demonstrated by the declarations of record. Second, the German reference does not anticipate the claims or render them obvious.

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*The German Reference Is Not Prior Art*

The declaration of inventor Thomas A. Simonton is filed with this response. At the time of the filing of the prior response, it was believed that the previously-filed Brown declaration along with the application information of record would suffice to remove the German reference. Further, in the interest of dispatch in responding to the prior non-final Office Action, a filing was desired on or prior to the three-month deadline, and at that time the Simonton declaration was not available. It is respectfully requested that the Examiner consider the Simonton declaration and reconsider the previously-file Brown declaration in connection with it.

The Simonton declaration and its exhibits show that the subject matter of this application was conceived prior to September 18, 2003, which is the publication date (and thus the effective date) of the German reference. Mr. Simonton is an inventor of that subject matter, and he noted that the other inventor, Dr. Gross, was not available to provide a declaration. Along with the declaration, exhibits showing drawings of the conceived-of subject matter are provided. As noted in the declaration, these drawings were prepared prior to September 18, 2003, and therefore evidence conception prior to that date.

This application's filing on Wednesday, September 24, 2003 is a constructive reduction to practice of its subject matter. Diligence from just before the reference date to the September 24 filing date is demonstrated in the Simonton declaration. Specifically, a draft of the application was received by Mr. Simonton prior to September 17, 2003, and as of September 17, 2003 the application was in the process of final review before filing. The Simonton declaration, corroborated by the Brown declaration filed previously, shows that the draft was sent to outside counsel on Monday, September 22, 2003, and execution documents were sent from outside counsel to the inventors that day. The documents were signed the next day, and were returned to outside

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counsel by overnight courier. The signed documents were received by the outside counsel on Wednesday, September 24, 2003, and the complete application was filed that day.

The previously-submitted Brown declaration should be considered in connection with the Simonton declaration insofar as it corroborates the Simonton declaration, and it also provides information concerning diligence from the attorney's perspective. A discussion of the Brown declaration was provided in the prior response, and that discussion is incorporated by reference into this paper.

Accordingly, the evidence of record shows a conception prior to September 18, 2003, and a patent application in the final process on and before September 17, 2003, culminating in a constructive reduction to practice on September 24, 2003. With the intervening weekend, there were only five business days between the day just before the German reference's effective date (September 17) and the reduction to practice (September 24). The days of September 22-24 saw steps by inventors, inside counsel and outside counsel toward filing a complete application, as set forth in the declarations, that were performed as quickly as they could be. As the MPEP notes, "Six days to execute and file application is acceptable." See MPEP 2138.06 (citing *Haskell v. Coleburne*, 671 F.2d 1362, 213 USPQ 192, 195 (CCPA 1982) (indicating that six otherwise unexplained days for review and filing of a draft is sufficiently diligent)). The facts of record establish prior conception and diligence from a time prior to the reference's effective date to a reduction to practice, and on that basis the German reference should be withdrawn.

*The German Reference Does Not Anticipate the Claims or Render Them Obvious*

The prior response touched on the substantive bases for withdrawing the German reference as well. Those positions are repeated and incorporated by reference into this response.

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The following remarks address comments in the pending Office Action and recap reasons why the German reference does not anticipate or render obvious pending claims.

The Examiner took the position that "chamfer" in claim 2 means "two surfaces meeting at an angle different from 90 degrees." No support for that definition was provided, and the Examiner is requested to make of record the document(s) he relied on for that definition or an affidavit pursuant to 37 CFR 1.104(d)(2), if it comes from his own knowledge. According to Merriam-Webster's Collegiate Dictionary (10th ed.), "chamfer" means a beveled edge. The slanted sides of item 3 in the German reference cannot be a "chamfer" as recited in claim 2, for at least two reasons. First, to do so would read out of the claim either the tapered portion of claim 1 or the chamfer of claim 2. Second, the slanted sides are not an edge, but extend along the entire side, from top to bottom. There is no beveled edge on any part of the slanted sides of item 3 of the German reference, and thus claim 2 is not anticipated.

The Examiner referred to U.S. Publication No. 2002/0107572, but did not clearly rely on it for a rejection, and only noted it "[r]egarding the rejection . . . wherein fixation device are [sic] used in combination with an intervertebral fusion device." It appears that refers to prior remarks showing that claims 21-24, 31, and 41-42 are not obvious over the German reference alone. The Examiner may consider that a case of obviousness is made by the combination of the German reference and the '572 Publication, but respectfully that rejection was not made. On this record, a *prima facie* case of obviousness of the subject matter of claims 21-24, 31, and 41-42 over the German reference alone has not been made, as discussed in the previous response.

The Examiner stated (page 3, lines 17-18 of the Office Action) that "[i]t further teaches oblique first and second surfaces, this is an official notice (MPEP 2144.03)." Regrettably, it is not clear which reference (the German reference or the '572 Publication) that sentence refers to.

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"Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known." MPEP 2144.03. If the Examiner is referring to a reference, he is respectfully requested to identify the reference and the features he believes correspond to "oblique first and second surfaces." If he is making an "official notice" under MPEP 2144.03, he is respectfully requested to identify what facts are asserted and how they are capable of instant and unquestionable demonstration as being well-known.

It has been noted above that the German reference does not show the chamfered end(s) of claim 2. It was observed in a previous filing that the binding agent of claim 3 and a member that stops short of an opposing side as in claim 5 are also not shown in the German reference, and the pending Office Action did not contest that fact. With respect to claim 12, the Office Action suggested (without identifying any reference) that hydroxylapatite and tricalcium phosphate were considered to be "bioglass." Without a reference, that assertion is not properly supported, and it is not believed to be correct. Bioactive glasses may include oxides of silicon, calcium, sodium and phosphorus (see [http://en.wikipedia.org/wiki/Bioactive\\_glass](http://en.wikipedia.org/wiki/Bioactive_glass), last accessed December 19, 2007). As to claim 11, the Office Action asserted (again without identifying any reference) that the implant body of the German reference can be made of metal. It teaches away from using metal. See, e.g., page 3, lines 18-22 and page 4, lines 14-15 of the previously-submitted translation of the German reference (specific ceramic material is comparable to bone and allows proper degradation, and making the implant radiotransparent creates an advantage in assessing fusion). These and other features of other claims are not shown in the German reference.

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The German reference rejects use of bone material for several reasons. See, e.g., page 2, line 10-page 3, line 17 of the previously-submitted translation of the German reference. Thus, the German reference actively counsels against use of any type of bone. One of ordinary skill also cannot glean a reasonable chance of success by using bone, since the German reference's disclosure "makes it possible to eliminate all of the drawbacks" alleged with non-synthetic material, i.e. bone. The German reference directly rebuts any suggestion that one of ordinary skill would have expected the German reference's device to perform equally well with bone materials taught by applicant, as it specifically opines that bone does not work as well as its fully synthetic material. It is not necessary for patentability for the Applicant to disclose advantages in using bone material, as the Office Action seemed to suggest. Rather, it is the PTO's burden to establish that claimed subject matter would be obvious, which is quite a high burden when a relied-on reference specifically discloses not to do what the pending claim proposes. Respectfully, the German reference is not silent as to the use of cancellous or cortical bone, when it discourages use of all bone material.

The pending Office Action again did not address the transfer of load from a bony structure to the recited body, as recited in claim 31. The German reference does not disclose any such transfer, and with the material 3 extending all the way through its item 1 and vertebrae contacting on top and bottom, the material 3 would transmit load between the vertebrae, rather than transferring it to item 1.

Furthermore, it is respectfully noted that the Office Action does not provide a sufficient basis for rejecting all of the claims over the German reference. It is "incumbent upon the Examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference." *Ex parte Levy*, 17 USPQ2d 1461, 1462 (Bd. Pat. App. & Inter. 1990). The  
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bottom of page 4 and the top half of page 5 of the pending Office Action constitute the sole analysis provided regarding claims 1-6, 10, 12, 16-17, 26, 28, 35-36 and 47-48. That text refers only to claims 1, 6, 12, 26 and 48. It is not conceded that the treatment of those four claims is sufficient, but clearly there is no analysis of record at all of claims 2-5, 10, 16-17, 28, 35-36 and 47. Respectfully, it is not possible to develop issues, or to meet the PTO's burden of proof for a rejection, concerning those claims.

#### Conclusion

It should be understood that this response is not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action but is simply provided to move this application to allowance in the most expedient fashion. Applicant reserves the right to later contest positions taken by the Examiner not specifically addressed herein, including arguing claims not specifically argued herein.

For at least the above reasons, withdrawal of the German reference and the rejections based on it is warranted. Applicants respectfully request a Notice of Allowance for the pending claims, and if any further issues remain, the Examiner is invited to call the undersigned.

Respectfully submitted,

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